

2. Rejections under 35 U.S.C. § 112

Claims 1-7, 9, 22, and 48 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness.

Claim 1 was rejected for indefiniteness of the phrases "characterized by" and "significant." The present Amendment removes the term "characterized by" from the claim, thereby obviating the rejection with respect to that phrase.

With respect to the phrase "significant", Applicant disagrees that the term is indefinite. Applicant points to Merriam-Webster's Collegiate Dictionary, which defines "significant" as "having or likely to have influence or effect" or "of a noticeably or measurably large amount" at definition 2a. Applicant respectfully submits that one of ordinary skill in the art would know what is meant by "significant concentrations of Se-methylselenocysteine" and "a significant amount of Se-methylselenocysteine," as recited in claim 1. Furthermore, Applicants submit that, since claim language is always interpreted in light of the specification, a person having ordinary skill in the art may read the specification and understand that a significant amount of Se-methylselenocysteine is an amount likely to have nutritional influence. *See, e.g.*, pages 6-7, lines 20-26 and Table 1, indicating guidelines of nutritionally significant quantities of metals set forth by the U.S. Department of Agriculture. Nonetheless, in order to further prosecution of the present case towards allowance, Applicant has amended claim 1 to specify "nutritionally significant".

The Examiner pointed out extraneous language between claims 2 and 3; Applicant apologizes for the error of inserting this language and has deleted it from the claims.

Claim 7 was rejected as indefinite because "it recites an improper Markush terminology". Claim 7 has been amended to recite proper Markush terminology, thereby obviating this rejection.

Claims 9 and 48 were rejected for indefiniteness for failing to recite the steps for incorporating the harvested plant portions into a processed food or a nutritional supplement, respectively. Applicant respectfully disagrees. Applicant points out techniques for preparing processed food or nutritional supplements are well-known in the art. The specification indicates that the inventive plant material, into which Se-methylselenocysteine has been incorporated, may be formulated into a processed food or nutritional supplement (see page 10, lines 11-19). The present invention is not limited to any particular mode or type of formulation, but rather

encompasses any natural, dried, or processed food or nutritional supplement including edible plant material with accumulated Se-methylselenocysteine. Applicant respectfully asserts that claims 9 and 48 are therefore not indefinite.

3. Rejections under 35 U.S.C. § 102

Claims 1-4, 9, and 48 were rejected under 35 U.S.C. § 102(b) as being anticipated by IP et al. (Nutrition and Cancer, vol. 20, no. 2, pp. 129-137, 1993 (U)) and Stoewsand et al. (Cancer Letters, vol. 45, pp. 43-48, (1989) (V)). Claim 22 was not rejected under 102(b) as being anticipated by either of the cited references, or any other prior art. Claim 22 incorporates the limitation that the accumulated Se is in the form of Se-methylselenocysteine. Claims 1-4, 9, and 48 have been amended to incorporate the limitation that the accumulated Se is in the form of Se-methylselenocysteine. Applicant respectfully submits that the amendments incorporating the limitation of claim 22, render the novelty rejection of the outstanding claims moot. Applicant addresses obviousness rejection of claim 22 and the amended claims below.

4. Rejections under 35 U.S.C. § 103

Claims 1-7, 9, and 48 were rejected under 35 U.S.C. § 103 as being obvious over Raskin et al. in view of Stoewsand et al. Claims 1-4, 7, and 48 have been amended to incorporate the limitation of claim 22, that the accumulated Se is in the form of Se-methylselenocysteine. The Examiner acknowledges that Raskin in view of Stoewsand does not teach the accumulated Se in the form of Se-methylselenocysteine. Therefore, Applicant respectfully submits that the amendments incorporating the limitation of Se-methylselenocysteine, render the obviousness-type rejection of the outstanding claims moot, with respect to Raskin in view of Stoewsand.

Examiner rejected claims 1-7, 9, 22 and 48 under 35 U.S.C. § 103 as being obvious over Raskin et al in view of Stoewsand et al., and further in view of Applicant's admitted prior art. Examiner points to Trelease et al., Virupaksha et al., and Shrift et al., as Applicant's admitted prior art. Examiner states that "[w]hile Raskin in view of Stoewsand do not teach the accumulated selenium in the form of methylselenocysteine, it is known in the prior art that the major Se-containing compound in Se-accumulator species is the Se-methylselenocysteine as evidenced by Applicant's admitted prior art. Therefore, one of ordinary skill in the art at the time the invention was made would expect that the majority of the accumulated selenium

compound in the accumulator plant would be in the form of Se-methylselenocysteine."

Applicant respectfully traverses this rejection.

First, Applicant submits that there is no motivation to combine Raskin with Trelease, Virupaksha and Shrift to obtain the claimed invention. Raskin does not point to a particular desire to accumulate selenium, as compared with other metals, and Trelease, Virupaksha and Shrift do not identify a need to find an alternative plant type into which selenium should be accumulated. Absent the teachings of the present specification, there is no motivation to even *try* to make the present invention by combining the cited reference.

Furthermore, even if there were such a motivation to try (and/or motivation to combine), there would be no reasonable expectation of success. Applicant points out that the particular plants utilized in the Trelease, Virupaksha and Shrift (i.e., members of the *Astragalus* genus), are not crop plants and furthermore are unusual in the plant world in their ability to accumulate selenium. Even if these plants accumulate selenium in the form of methylselenocysteine, there is no reason to expect that crop plants would do the same. In fact, their extraordinary ability to accumulate selenium *differentiates them* from other plants, so that it might be expected that other plants would accumulate selenium in a different way, as a different form, and/or to a different extent.

Furthermore, the *Astragalus* plants described in the cited references are all plants that accumulate metal ions on or in their roots. The present claims recite methods in which *crop* plants accumulate Se-methylselenocysteine in their *edible portions*. Such edible portions are typically leaves. There is no teaching or suggestion in the cited references that *Astragalus* plants, let alone any other kind of plants, can transport metal ions accumulated in or on their roots to other parts of the plant. Metal ions are charged and therefore cannot move freely across cellular membranes, which are lipophilic structures. Therefore, ion transport into cells is generally mediated by membrane proteins with transport functions (e.g., transporters). Only a small fraction of the ions that associate with a plant root become absorbed into cells. A significant ion fraction is physically absorbed at the extracellular negatively charged sites of the root cell walls. The cell wall-bound fraction cannot be translocated to the shoots or leaves. Furthermore, even ions that make it into cells often become complexed and sequestered in cellular structures (e.g., vacuoles), similarly unable to be translocated to shoots or leaves.

For all of these reasons, Applicant respectfully submits that the presently pending claims are not obvious over the cited art, and the rejection should be removed.

5. Rejection for Double Patenting

Claims 1-7, 9, 22, and 48 were rejected under the judicially created doctrine of non-obviousness-type double patenting as being unpatentable over claims 11-21 of US patent 6,117,462 (the '462 patent). The patent claims and the pending claims differ in several respects including, for instance, that the patent claims require application of an inducing agent and are not limited to selenium accumulation, and specifically to accumulation of selenium as methylselenocysteine. The present claims are patentably distinct from these claims.

Enclosed herein is a marked-up version of the changes made to the claims by the current amendment (Appendix A). Enclosed herein also is a clean copy of all pending claims in the form they will take after entrance of the present amendment (Appendix B). In light of the foregoing Remarks and Amendments, Applicant respectfully submits that the present case is in condition for allowance. A Notice to that effect is respectfully requested.

If, at any time, it appears that a phone discussion would be helpful or if questions arise regarding the amendments proposed above, please do not hesitate to contact the undersigned at (617) 248-5175.

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Appendix AVersion With Markings to Show Changes Made

1. A method of producing an edible plant whose edible portions comprise nutritionally significant concentrations of Se-methylselenocysteine [or selenium], comprising:
  - identifying a growth environment containing Se-methylselenocysteine [selenite];
  - providing a crop plant having [characterized by] an ability to accumulate Se-methylselenocysteine in its edible portions;
  - cultivating the plant in the growth environment under conditions and for a time sufficient for the plant to accumulate a nutritionally significant amount of Se-methylselenocysteine [or selenium] in its edible portions;
  - and harvesting edible portions of the plant which comprise accumulated Se-methylselenocysteine [selenium].
2. The method of claim 1, where the growth environment contains Se-methylselenocysteine [selenite].  
[Already said.]
3. The method of claim 1, where identifying the growth environment includes manipulating the growth environment to increase the availability of Se-methylselenocysteine [selenite] to the plant.
4. The method of claim 3, where manipulating the growth environment includes adding Se-methylselenocysteine [selenite] to the growth environment.
7. The method of claim 6, where the plant is a member of the species *Brassica juncea*, *Brassica oleracea* [Oleracea], or [and] *Brassica carinata* [Carinata].
22. [Cancelled.]
48. A method of providing a nutritional supplement, comprising:

providing a plant that contains Se-methylselenocysteine [or selenium] in its edible portions; and incorporating the plant into a nutritional supplement.